



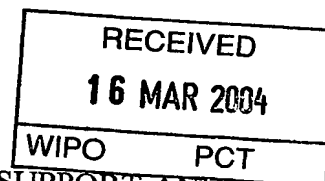
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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002953483 for a patent by DRUG DELIVERY SOLUTIONS PTY LTD as filed on 20 December 2002.

I further certify that the name of the applicant has been amended to ACRUX DDS PTY LTD pursuant to the provisions of Section 104 of the Patents Act 1990.



WITNESS my hand this
Eleventh day of March 2004

J. Billingsley

JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES

AUSTRALIA
Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: USAGE INDICATOR

Applicant: DRUG DELIVERY SOLUTIONS PTY. LTD.

The invention is described in the following statement:

USAGE INDICATOR

This invention relates to means for indicating the extent to which a device has been used. The invention has particular, but not exclusive, application to devices for dispensing a substance, such as a pharmaceutical, medicinal, or therapeutic substance. It will be convenient to hereinafter describe the invention with reference to such dispensing devices intended for transdermal and/or percutaneous delivery of substances, but it is to be understood that the invention has broader application.

It is usually the case that substance dispensing devices of the foregoing kind can be used on several occasions before the quantity of the substance stored in the device is exhausted. It is also a common requirement that an accurately metered amount of the substance is dispensed each time the device is operated.

Devices of the foregoing kind have been provided with means that enable the user to determine when the stored quantity of the substance is getting low. Various different arrangements have been provided for that purpose, but they have not been entirely satisfactory because of cost, lack of accuracy, or difficulty to read or interpret.

Another problem encountered with devices of the foregoing kind is the possibility of the device dispensing less than the intended quantity of the substance. That may occur because of inadequate care on the part of the operator, and may also occur because the stored quantity of the substance remaining in the device is too small at the time the device is operated.

It is an object of the present invention to provide a relatively inexpensive, accurate and easy to read usage indicator. It is a further object of the present invention to provide a substance dispensing device including such an indicator. Still another object of the invention is to provide a substance dispensing device having a usage indicator, and also having means preventing operation of the device when the quantity of the stored substance approaches exhaustion.

A usage indicator according to the present invention is characterised in that it includes a member that responds to operation of the device with which it is used, and indicator means associated with that member and arranged to provide a visual indication of the extent to which the device has been used. The

visual indication provided by the indicator means may increase in a progressive manner in response to each operation of the associated device.

In a preferred arrangement, the aforementioned member moves in response to movement of an actuator of the associated device. The actuator
5 may be moved away from a rest position in order to operate the device, and then returned to the rest position to enable further operation of the device. It is preferred that the movable member moves in response to movement of the actuator away from the rest position, and also moves in response to movement of the actuator back towards the rest position. That two-stage movement of the
10 movable member is preferably representative of a single operation of the device.

A device including a usage indicator according to the present invention may also include use prevention means that is responsive to the usage indicator so as to prevent operation of the device when the device has been
15 operated on a predetermined number of occasions. That number may correspond to the number of operations required to exhaust, or substantially exhaust a predetermined quantity of a substance that is initially stored by the device. Preferably, the number of operations is selected to ensure that the intended quantity (full dose) of the substance is dispensed during the last
20 operation of the device.

It will be convenient to hereinafter describe the invention in greater detail by reference to the accompanying drawings showing an example embodiment of the invention. The particularity of the drawings and the related description of those drawings is not to be understood as superseding the generality of the
25 preceding broad description of the invention. The drawings show the usage indicator of the invention associated with a substance dispensing device, but as previously stated the invention is applicable to other types of devices.

Figure 1 shows an example substance dispensing device 1 associated with a usage indicator 2 according to one embodiment of the invention. The
30 device 1 includes a substance storage container 3 and a pump 4 operable to pressurise the contents of the container 3 and thereby induce a quantity of the substance to be expelled through a nozzle 5, possibly in the form of a spray or mist. The pump 4 may be of a known kind that operates in a known manner in response to downward movement of the nozzle head 6 of the pump 4. In the

particular arrangement shown, an actuator button 7 overlies the head 6 and cooperates with that head so that depression of the button 7 causes downward movement of the head 6. An opening 8 formed through a side wall of the button 7 is aligned with the nozzle 5 so as to allow passage of the substance expelled through the nozzle 5.

It is to be understood that the usage indicator 2 could be used with other types of dispensing devices, including aerosol-type dispensers.

In the arrangement shown by Figure 1, the usage indicator 2 is located between two supports or retainers 9 and 10 that hold the indicator 2 against movement with the actuator button 7. The retainers 9 and 10 can be of any suitable form or construction. As hereinafter described in greater detail, the usage indicator 2 responds to operational movement of the actuator button 7 so as to indicate the extent to which the device 1 has been used.

Figure 1 shows the button 7 in a rest position. Downward movement of the button 7 from that rest position causes operation of the pump 4, and it is preferred that biasing means functions to return the button 7 to the rest position when downward pressure is removed from the button 7. It is further preferred that the usage indicator 2 responds to downward movement of the button 7 away from the rest position, and also responds to return movement of the button 7 towards the rest position. That two-stage response is preferably representative of a single operation of the device 1.

Figure 2 illustrates an example housing 11 for the dispensing device 1. The housing 11 includes a hollow body 12 for accommodating the container 3 and the pump 4, and a shroud 13 defining a space for receiving substance expelled through the nozzle 5. The usage indicator 2, or indicating means associated with the indicator 2, may be observable through an aperture or window 14 provided in a side wall of the body 12. A removable dust cap 15 may be located over the open mouth of the shroud 13 when the device 1 is not in use.

Figure 3 is an exploded view of an assembly comprising the dispensing device 1, the device housing 11, and one particular form of usage indicator 2 according to the invention. In that assembly, the usage indicator 2 is supported or retained by location between two internal ledges 9 and 10 of the housing 11.

A part of each ledge 9 and 10 may be provided in each of the two halves of the housing 11 shown by Figure 3.

The particular usage indicator 2 shown in the accompanying drawings includes a member 16 that is mounted for rotation relative to the device housing 11. As shown, the member 16 is of cylindrical tubular form, but other forms could be adopted. Also, in the arrangement shown, the member 16 is rotatable about the longitudinal axis 17 of the device 1 (Figures 1 and 3), but that is not essential. Interactive means is provided to enable operational movement of the actuator button 7 to cause rotation of the member 16. Since the button 7 moves in the direction of the rotational axis 17 of the member 16, the interactive means includes means for converting linear movement of the button 7 into rotational movement of the member 16. For that purpose, the interactive means may include drive means connected to the button 7, and reactive means connected to the member 16 and positioned for engagement by the drive means during linear movement of the button 7. The drive means and the reactive means are preferably arranged so that during linear movement of the button 7, the drive means and the reaction means coact in a manner such that the member 16 is caused to rotate.

In the example shown, the drive means includes two drive lugs 18 and 19 that are connected to or formed integral with a lower skirt portion 20 of the actuator button 7. The drive lugs 18 and 19 are spaced apart in the direction of the axis 17 for a reason hereinafter made clear. A sloping face 21 is provided at the lower end of the uppermost lug 18, and a similar sloping face 22 is provided at the upper end of the lowermost lug 19. The sloping faces 21 and 22 are in opposed relationship, but as best seen in Figures 4 to 8 they slope in opposite directions – for example, at substantially 90° to one another. It is preferred, as shown by Figure 9, that the face 21 extends outwards from the skirt portion 20 through a distance greater than the outward extension of the face 22.

One form of reactive means suitable for coaction with drive means of the foregoing kind includes two circular series of teeth, 23 and 24 respectively, connected to or formed integral with an upper edge portion of the member 16. In the arrangement shown, both series of teeth extend around the full circumference of the member 16, but that may not be the case in other

embodiments of the invention. The teeth 23 and the teeth 24 are preferably of "saw-tooth" form as shown, but again that is not essential, and may not be adopted in other embodiments of the invention. As best seen in Figures 4 to 8, each tooth 23 has an upwardly facing sloping face 25 that is preferably substantially parallel to the face 21 of the lug 18, and each tooth 24 has a downwardly facing sloping face 26 that is preferably substantially parallel to the face 22 of the lug 19.

Figures 4 to 8 provide a diagrammatic representation of the manner in which the lugs 18 and 19 cooperate with the teeth 23 and 24 respectively. Those Figures are representative of a cross-sectional view of the member 16, and consequently show the teeth 23 and 24 in the same disposition as that shown at the remote side of the member 16 as it appears in Figure 3. It is particularly important to note that the interaction between the lugs 18 and 19 and the teeth 23 and 24 as shown by Figures 4 and 8, causes the member 16 to rotate in the anti-clockwise direction as indicated by the arrows A in Figure 3. Subsequent reference in this specification to the "leading side" or "trailing side" of a part of the assembly is to be understood as referring to travel in the direction of arrows A.

When the usage indicator 2 is installed on the device 1, the two series of teeth 23 and 24 are both located between the drive lugs 18 and 19, as shown by Figures 4 to 8. Downward movement of the button 7 in the direction of arrow D (Figure 4) brings the face 21 of the lug 18 into engagement with the face 25 of a tooth 23a (Figure 5). Continued downward movement of the button 7 produces a coaction between the faces 21 and 25 such that the member 16 is caused to rotate to the left as shown by Figure 6. At that stage, the button 7 has been depressed to its full extent and the pump 4 has been operated as required. Release of pressure on the button 7 then allows associated biasing means to move the button 7 upwards in the direction of arrow U (Figure 6) towards the rest position. The face 22 of the lug 19 is thereby brought into engagement with the face 26 of a tooth 24a (Figure 7). Continued upward movement of the button 7 then causes the member 16 to be rotated further to the left (Figure 8).

When the member 16 is at the position shown by Figure 6, it has been shifted to the left (from the Figure 5 position) by approximately one half of an

increment of the movement intended for the member 16 in response to each operation of the pump 4. When the member 16 is at the position shown by Figure 8, it has moved to the left (from the Figure 5 position) through a complete increment of movement. The tooth 23a which is engaged by the lug 18 in the Figure 5 position, is now located to the left out of the path of the lug 18. Another tooth, 23b, is now located in the path of the lug 18 and will be engaged by that lug when the device 1 is next operated.

The increment of movement of the member 16 that occurs with each operation of the device 1, is through a distance substantially equal to the length of a tooth 23. That is, it is substantially equal to the distance between the upright faces 27 of two adjacent teeth 23 (Figure 4).

The number of teeth in each series of teeth 23 and 24 will be selected according to requirements. One factor of possible influence is the number of operations of the pump 4 required to completely exhaust, or substantially exhaust, the stored contents of the container 3.

Part of the outer surface 28 of the member 16 may be observable through the window 14. Any suitable indicator means may be provided on the surface 28 (Figure 3) to indicate, at the window 14, the extent to which the device 1 has been operated. By way of example, the indicator means may be a series of numbers, a respective one of which becomes observable at the window 14 after each operation of the device 1. In the particular example shown by Figure 3, the indicator means is a band 29, possibly of a distinctive colour, that progressively changes in width around the circumference of the member 16. Only a small segment of the band 29 is observable at the window 14 at any one point in time. A maximum width segment of the band 29 may be visible at the window 14 when the device 1 is to be operated for the first time, and a minimum or zero width segment may be visible when there is little or no substance remaining in the container 3.

In some circumstances the number of possible operations of the pump 4 may exceed the number of teeth 23 capable of being provided on the member 16. That is, the member 16 must be moved through more than one complete revolution in order to exhaust, or substantially exhaust, the contents of the container 3. One solution to that problem is to provide the usage indicator 2 with a second movable member 30 (Figure 3) that provides an indication of the

extent of use of the device 1 during part of the time the pump 4 is capable of effective operation. In that regard, "effective operation" is to be understood as operation capable of delivering a substantially complete dose, or metered quantity, of the stored substance through the nozzle 5.

5 Figure 3 illustrates an example arrangement involving use of a second movable member 30. In that particular arrangement, both members 16 and 30 are of cylindrical tubular form, and the second member 30 is located over the member 16. It will be convenient to hereinafter refer to the members 16 and 30 as the inner and outer members respectively. Indicator means 31 is provided
10 on the outer surface 32 of the outer member 30, and it is preferred (as shown) that the indicator means 31 is of a style consistent with the style of the indicator band 29 of the inner member 16. It is particularly preferred that each of the two indicator bands 29 and 31 form a respective part of a continuous sequence of use indications. As previously stated, indicator means other than a band-type
15 indicator means may be employed.

 In the example arrangement of Figure 3, the two members 16 and 30 are arranged so that the outer member remains stationary while the inner member 16 is rotated through a first series of increments of movement. That first series may be equal to, or substantially equal to, a complete revolution of the inner
20 member 16. At the end of that first series of movements however, the two members 16 and 30 become connected in a manner such that further rotation of the inner member 16 causes corresponding rotation of the outer member 30. It is preferred that the indicator band 29 of the inner member 16 is observable at the window 14 during the first series of increments of movement, and that the
25 indicator band 31 of the outer member 30 becomes observable at the window 14 after that first series has been completed. For that purpose, an opening 33 may be provided through a wall of the outer member 30 so as to be aligned with the window 14 when the member 30 is at an initial inactive position relative to the device body 12. The indicator band 29 of the inner member 16 is therefore
30 observable through the window 14 and the aligned opening 33.

 Releasable stop means, of any appropriate form, may be employed to hold the outer member 30 against rotation with the inner member 16 during the first series of increments of movement. In the particular example shown by Figure 3, such stop means includes a detent 34 provided on the outer member

30, and a cooperable recess 35 provided on an inner surface of the housing body 12. The detent 34 may be connected to the main body of the outer member 30 through a flexible arm 36 so as to permit the detent 34 to be disengaged from the recess 35 in circumstances hereinafter described. Other means may be adopted for that purpose.

Any suitable connecting means may be employed to connect the members 16 and 30 for simultaneous rotation after completion of the first series of incremental movements of the member 30. In the particular example shown by Figure 3, the connecting means includes at least one drive abutment 37 provided on the outer surface 28 of the inner member 16, and at least one cooperable abutment 38 provided on an inner surface of the outer member 30. Before initial operation of the device 1, the drive abutment 37 may be located against, or close to, the right-hand or leading side of the cooperable abutment 38. Each time the device 1 is operated, the drive abutment 37 will be moved (in an anti-clockwise direction as shown by the arrows A in Figure 3) further away from the right-hand side of the cooperable abutment 38. When the inner member 16 approaches completion of a full revolution, the drive abutment 37 engages the left-hand or trailing side of the cooperable abutment 38, and at that time the two members 16 and 30 become connected for simultaneous rotation.

When the device 1 is operated immediately following engagement of the abutments 37 and 38, the inner member 16 imposes a turning force on the outer member 30 that is sufficient to cause the detent 34 to be released from engagement with the recess 35. For that purpose, the detent 34 and/or the recess 35 may be provided with at least one sloping side surface that produces a camming action when pressed against an opposing surface of the recess 35 and/or the detent 34. The camming action is such as to induce the detent 34 to move out of the recess 35, and that movement is made possible by the flexibility of the arm 36.

The outer member 30 is thereby freed to rotate with the inner member 16. At the commencement of that simultaneous rotation the opening 33 is moved out of alignment with the window 14, and a segment of the indication band 31 of the outer member 30 becomes observable at the window 14. The indication band 29 of the inner member 16 is no longer observable because of the shift in the position of the opening 33.

It is preferred that the device 1 is provided with interlock means that is operative to prevent operation of the device 1 when there is little or no substance remaining in the container 3. In the preferred arrangement hereinafter described, the interlock means is responsive to the usage indicator so as to be rendered operative when the device 1 has been operated a predetermined number of times. It will be appreciated that other arrangements could be adopted.

The example interlock shown by Figure 3 includes a locking bar 40 that extends generally in the direction of the axis 17 and is located within the housing body 12 between the inner surface of that body and the outer member 30 of the usage indicator 2. A lower end 41 of the bar 40 may be secured to an inside surface of the housing body 12 in any appropriate manner. A head portion 42 at the upper end of the bar 40 is engageable within an interlock recess 43 of the outer member 30 in appropriate circumstances as hereinafter described. An intermediate portion 44 of the bar 40 is sufficiently flexible to allow the head portion 42 to move between inoperative and operative positions as hereinafter described.

When the device 1 is conditioned for initial operation, the interlock head portion 42 is positioned to one side of the recess 43, and is therefore at an inoperative position. In the particular arrangement shown by Figure 3, the head portion 42 is initially located relative to the recess 43 so that clockwise movement of the outer member 30 in the direction of arrows A (Figure 3) progressively moves the recess 43 into alignment with the head portion 42. The initial relative positioning of the head portion 42 and the recess 43 will be selected according to the extent to which the outer member 30 is intended to be rotated before the interlock becomes operative. During that rotation of the outer member 30, the intermediate portion 44 of the bar 40 remains in a resiliently distorted state such that the head portion 42 is pressed against the outer surface 32 of the outer member 30.

At completion of the intended rotational movement of the outer member 30, the recess 43 is aligned with the head portion 42, thereby allowing the head portion 42 to snap engage within the recess 43 and thereby adopt an operative position. Further rotation of the outer member 30 is prevented by that engagement, and further rotation of the inner member 16 is also prevented

because of engagement between the abutments 37 and 38. Such prevention of rotation of the member 16 and 30 may be sufficient to prevent further operation of the device 1. It is preferred however, that the interlock bar 40 also functions to prevent further operation of the device 1. For that purpose, the bar 40 is arranged to prevent the actuator button 7 being moved downward from the rest position to an extent such that coaction can occur between the lug 18 and a tooth 23 of the usage indicator 2. As will be apparent from the foregoing description, such coaction is necessary in order for the device 1 to operate.

Such locking of the actuator button 7 may be effected in any suitable manner. In the particular arrangement shown however, when the head portion 42 is within the recess 43, it is positioned directly beneath the lower edge 45 of the button 7. Downward pressure on the button 7 therefore results in the lower edge 45 engaging the head portion 42, and further downward movement of the button 7 is prevented.

It may be desirable to limit operation of the pump 4 to part only of the available downward travel of the button 7. In such circumstances a suitable lost motion facility may be incorporated in the device 1, or associated with the device 1. One such lost motion facility is shown in the example arrangement of Figure 3. In that arrangement the button 7 is normally held elevated from the nozzle head 6 by a coil compression spring 46. The spring 46 may form at least part of the biasing means that functions to return the button 7 to the rest position after each operation of the device 1. Another part of that biasing means may be formed by a return spring (not shown) for the pump 4. It is preferred as shown, that the spring 46 acts between the button 7 and a cap 47 positioned over the nozzle head 6. The cap 47 has an opening 48 that is aligned with both the nozzle 5 and the button opening 8 so as to allow passage of substance expelled through the nozzle 5.

The arrangement is preferably such that operation of the pump 4 does not commence until the button 7 engages against an upper end 49 of the cap 47 and thereafter presses the cap 47 downwards. The nozzle head 6 moves downwards with the cap 47 and thereby causes operation of the pump 4 in a known manner. It is preferred that the lug 18 does not engage with a tooth 23 of the usage indicator 2 until operation of the pump 4 commences, or is about to commence.

Retaining means may be provided to prevent rotational movement of the button 7 out of the position at which the opening 8 is aligned with the nozzle 5. The same means, or different means, may be adopted to prevent rotational movement of the cap 47 out of the position at which the opening 48 is aligned with the nozzle 5.

In the Figure 3 arrangement, the retaining means includes guide means acting between the button 7 and the housing body 12. In the example shown, that guide means includes a guide rib 50 provided on an inner surface of the body 12, and a cooperative guide groove 51 provided on the outside surface of the button 7. Both the rib 50 and the groove 51 extend generally in the direction of the axis 17, and the guide rib 50 is slidably located within the groove 51.

Similar guide means may be provided between the button 7 and the cap 47. In the arrangement shown by Figure 3, at least one guide rib 52 is provided on an inside surface of the button 7 and is slidably located in a cooperative recess 53 provided in a laterally extending flange 54 of the cap 47. That arrangement prevents relative rotation of the button 7 and the cap 47, but permits the button 7 to be moved downwards relative to the cap 47. Other arrangements could be adopted to achieve the same result. Relative rotation between the cap 47 and the nozzle head 6 may be prevented, or resisted, by forming the cap 47 so that it is a press fit on the nozzle head 6.

Any suitable means may be adopted to ensure, or encourage, proper location of the device 1 within the housing 11 such that the nozzle 5 is aligned with the shroud 13.

It will appear from the foregoing description that the present invention provides a relatively simple, accurate, and easy to read usage indicator for devices intended to be operated or used on a number of occasions. The inclusion of an interlock that is responsive to the usage indicator can be of significant benefit in at least some circumstances.

Finally, it is to be understood that various alterations, modifications and/or additions may be introduced into the constructions and arrangements of

parts previously described without departing from the spirit or ambit of the invention.

DATED: 20 December 2002

5 PHILLIPS ORMONDE & FITZPATRICK

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DRUG DELIVERY SOLUTIONS PTY LTD

David B Fitzpatrick

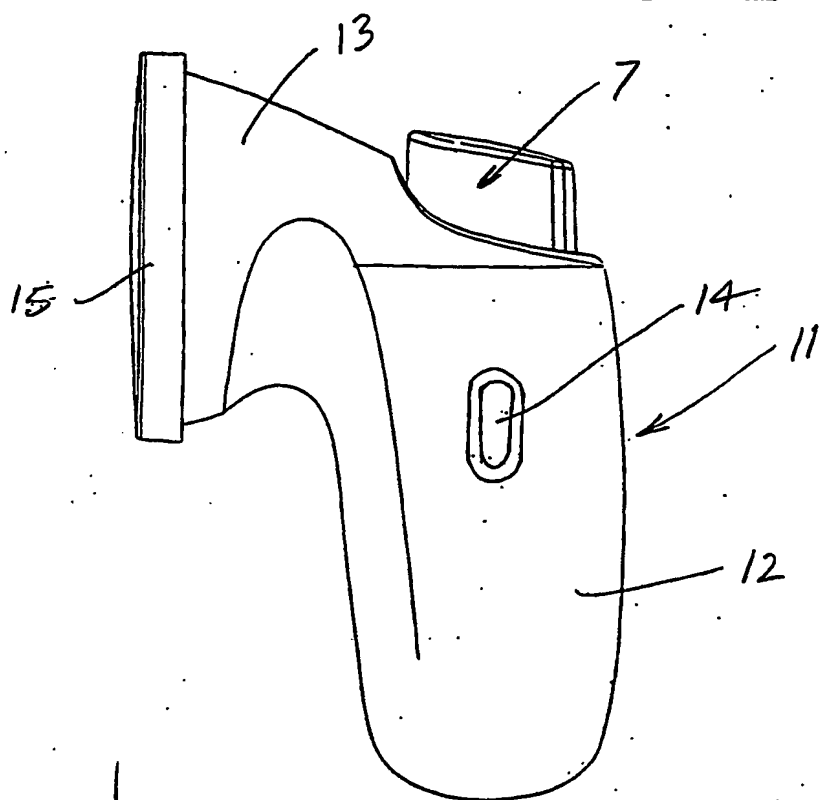


FIG. 2.

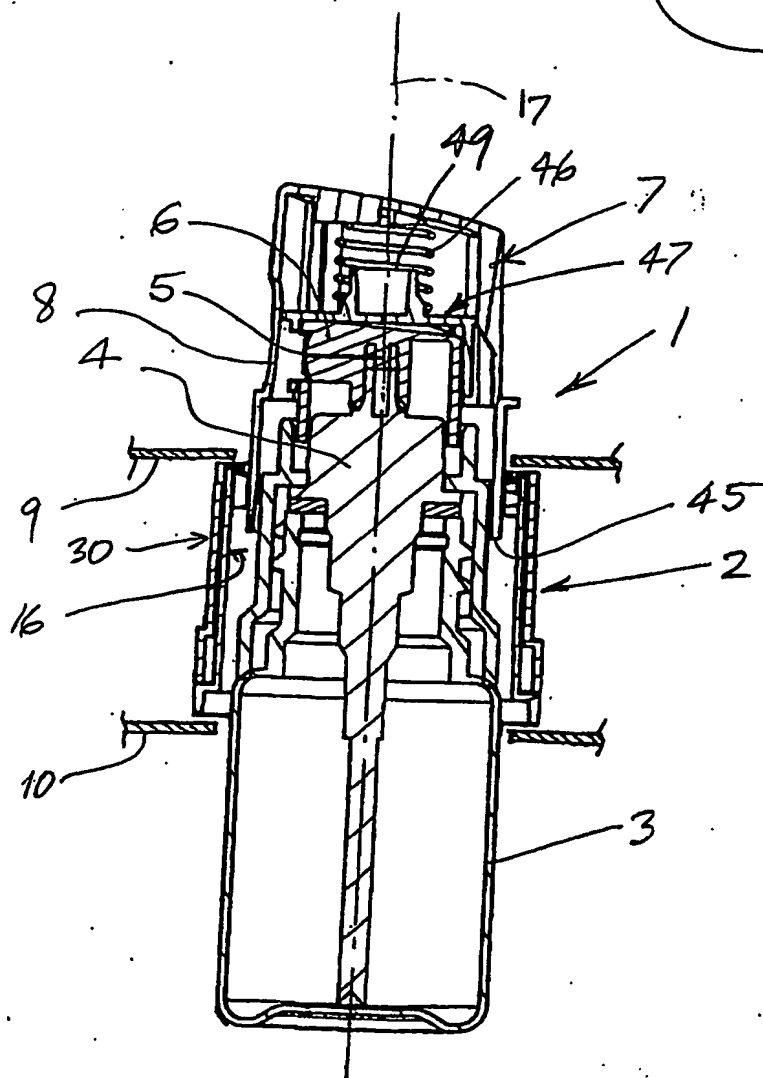


FIG. 1.

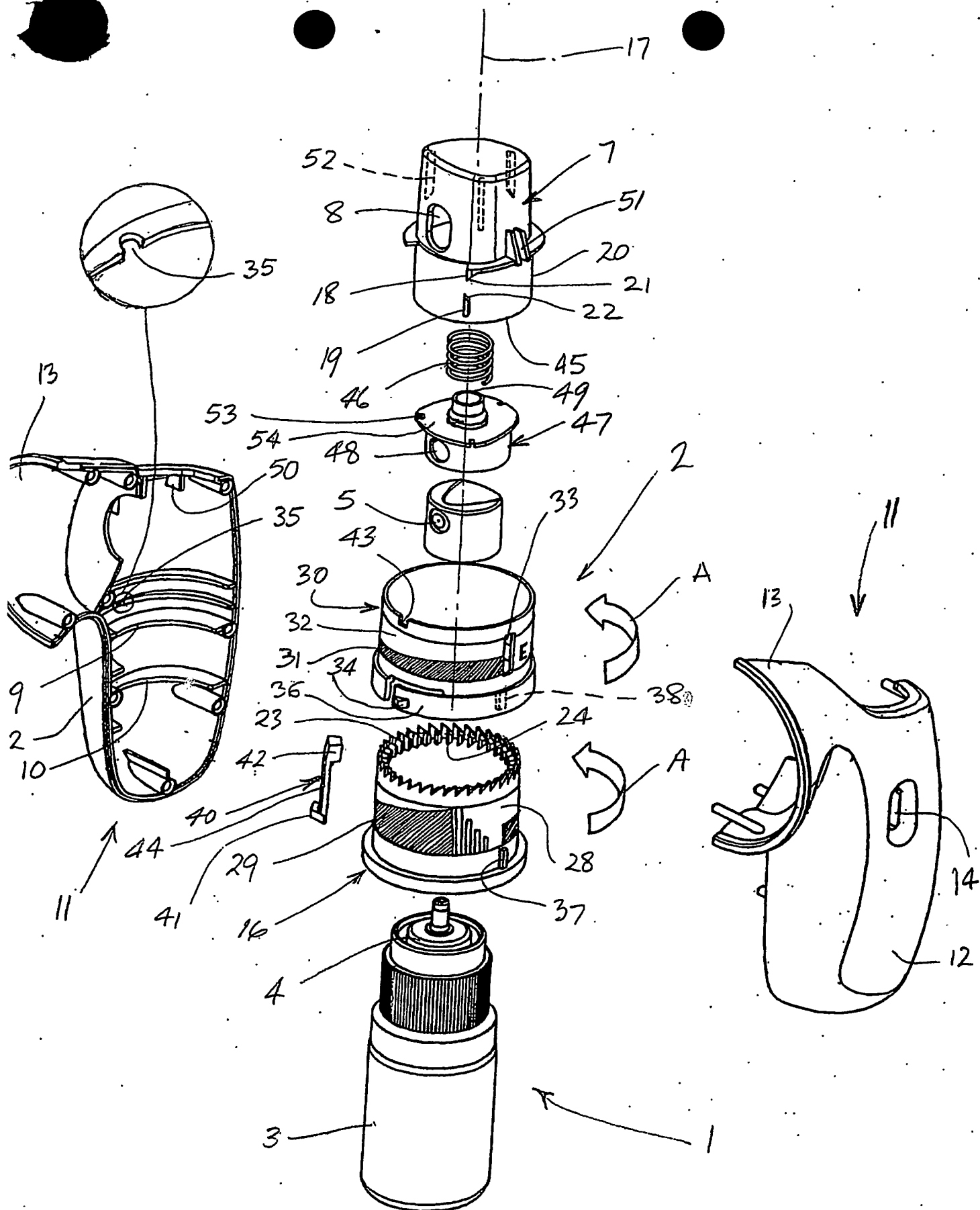


FIG. 3.

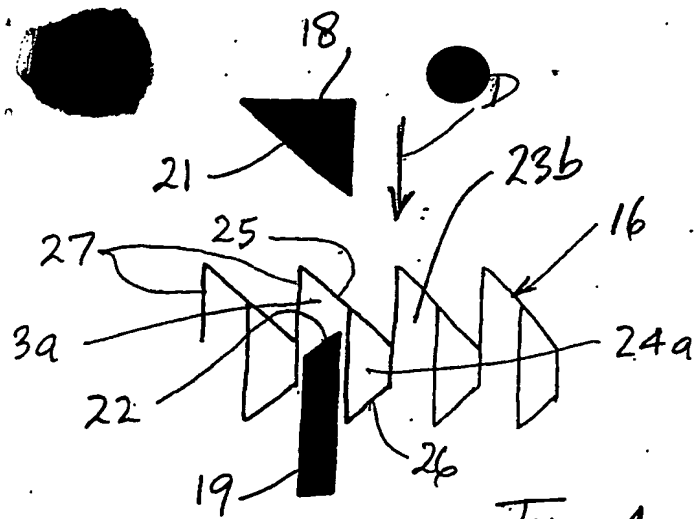


FIG. 4

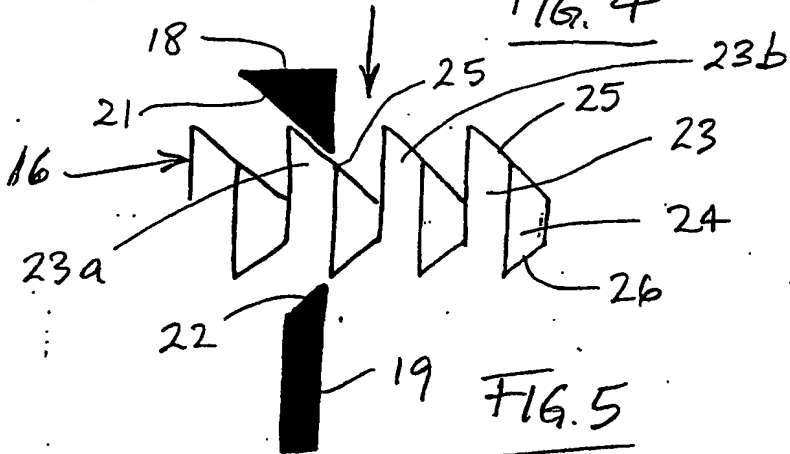


FIG. 5

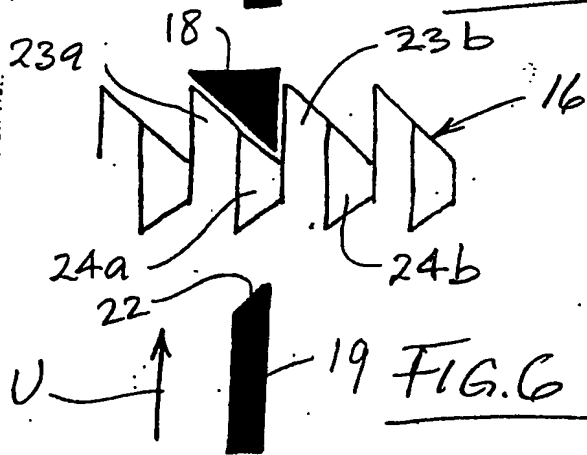


FIG. 6

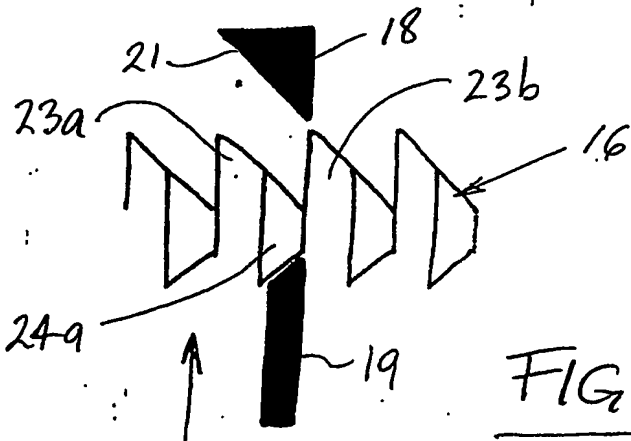


FIG. 7.

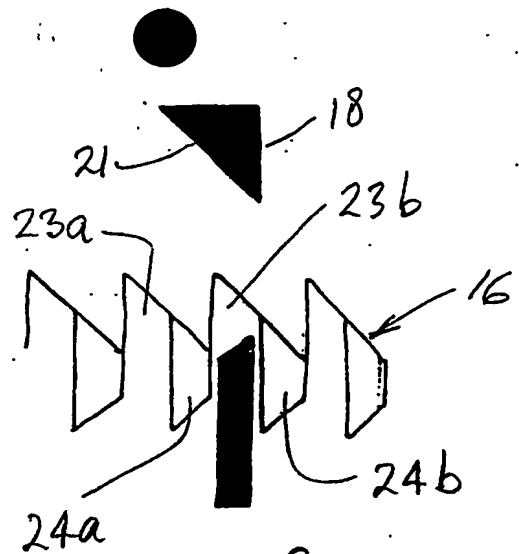


FIG. 8

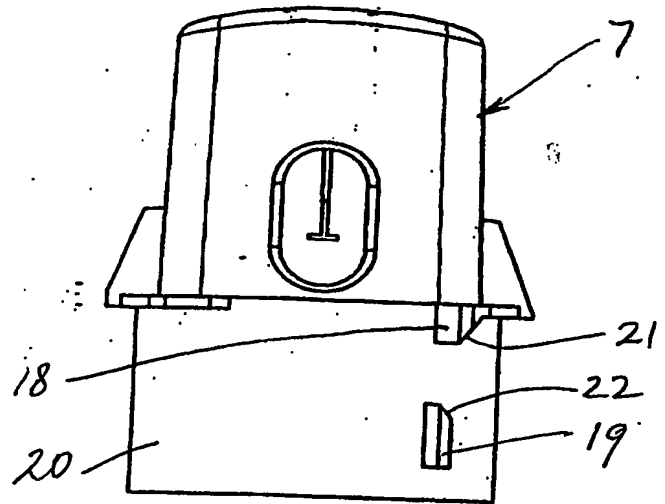


FIG. 9.